



Memorandum

FEB 06 2004

Date: \_\_\_\_\_  
From: Interdisciplinary Scientist/Pharmacist, Division of Dietary Supplement Programs  
, Office of Nutritional Products, Labeling and Dietary Supplements, HFS-810  
Subject: 75-Day Premarket Notification of New Dietary Ingredients  
To: Dockets Management Branch, HFA-305

Subject of the Notification: Eighteen Buddha To Da Wan  
Firm: New Century Company  
Date Received by FDA: 7/22/03  
90-Day Date: 10/21/03

In accordance with the requirements of section 413(a) of the Federal Food, Drug, and Cosmetic Act, the attached 75-day premarket notification and related correspondence for the aforementioned substance should be placed on public display in docket number 95S-0316 as soon possible since it is past the 90-day date. Thank you for your assistance.

Maria Chang

95S-0316

RPT206



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Public Health Service

Food and Drug Administration  
College Park, Maryland 20740

OCT - 6 2003

David Hsu, President  
New Century Company  
3392 Falcon Ridge Road  
Diamond Bar, California 91765

Dear Mr. Hsu:

This is to inform you that the notification, dated July 13, 2003, you submitted on behalf of your client, Sunray Inc. pursuant to 21 U.S.C. 350b(a)(2)(section 413(a)(2) of the Federal Food, Drug, and Cosmetic Act (the Act)) was filed by the Food and Drug Administration (FDA) on July 22, 2003. Your notification concerns the substance called "Eighteen Buddha Ta Da Wan", that you intend to market as a new dietary supplement.

According to the notification, you recommend taking one 2-gram (g) caplet per day. The notification states that the maximum dosage is 2 caplets or 4 g per day and the duration of product use is one year. You state that the structure/function statement will be "This formula helps your muscle health."

Under 21 U.S.C. 350b(a)(2), the manufacturer or distributor of a dietary supplement that contains a new dietary ingredient that has not been present in the food supply as an article used for food in a form in which the food has not been chemically altered must submit to FDA, at least 75 days before the dietary ingredient is introduced or delivered for introduction into interstate commerce, information that is the basis on which the manufacturer or distributor has concluded that a dietary supplement containing such new dietary ingredient will reasonably be expected to be safe. FDA reviews this information to determine whether it provides an adequate basis for such a conclusion. Under section 350b(a)(2), there must be a history of use or other evidence of safety establishing that the new dietary ingredient, when used under the conditions recommended or suggested in the labeling of the dietary supplement, will reasonably be expected to be safe. If this requirement is not met, the dietary supplement is deemed to be adulterated under 21 U.S.C. 342(f)(1)(B) because there is inadequate information to provide reasonable assurance that the new dietary ingredient does not present a significant or unreasonable risk of illness or injury.

FDA has carefully considered the information in your submission, and the agency has significant concerns about the evidence on which you rely to support your conclusion that a dietary supplement containing "Eighteen Buddha Ta Da Wan"(blackberry current powder, 0.12 g; blackberry powder, 0.08 g, and oil of sweet birch powder, 0.005 g) will reasonably be expected to be safe.

The notification does not clearly identify which components in the dietary supplement "Eighteen Buddha Ta Da Wan" are the new dietary ingredients. For example, the notification states that "the new dietary supplement ingredients include black current powder (Ribes nigrum), blackberry powder (Cimicifuga racemosa), and oil of sweet birch powder (Betula alba L.)". According to the literature submitted in the notification the common name of Cimicifuga racemosa is black cohosh. However, the notification identifies the botanical source of blackberry powder as Cimicifuga racemosa. Based on the notification submitted, the new dietary ingredients contained in the dietary supplement called "Eighteen Buddha Ta Da Wan" are unclear.

Moreover, the notification does not contain any information regarding the history of use of "Eighteen Buddha Ta Da Wan" nor does it contain any safety information regarding "Eighteen Buddha Ta Da Wan".

For the reasons discussed above, the information in your notification does not provide an adequate basis to conclude that "Eighteen Buddha Ta Da Wan," when used under the conditions recommended or suggested in the labeling of your product, will reasonably be expected to be safe. Therefore, your client's product may be adulterated under 21 U.S.C. 342(f)(1)(B) as a dietary supplement that contains a new dietary ingredient for which there is inadequate information to provide reasonable assurance that such ingredient does not present a significant or unreasonable risk of illness or injury. Introduction of such a product into interstate commerce is prohibited under 21 U.S.C. 331(a) and (v).

Your notification will be kept confidential for 90 days after the filing date of July 22, 2003. After the 90-day date, the notification will be placed on public display at FDA's Docket Management Branch in docket number 95S-0316. Prior to that date, you may wish to identify in writing specifically what information you believe is proprietary, trade secret or otherwise confidential for FDA's consideration.

If you have any questions concerning this matter, please contact Victoria Lutwak at (301) 436-2375.

Sincerely yours,



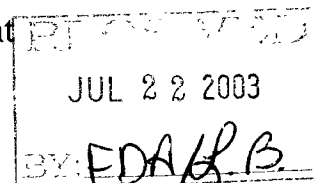
Susan J. Walker, M.D.  
Division Director  
Division of Dietary Supplement Programs  
Office of Nutritional Products, Labeling  
and Dietary Supplements  
Center for Food Safety  
and Applied Nutrition

## NEW CENTURY COMPANY

3392 Falcon Ridge Rd., Diamond Bar, CA 91765 U.S.A.

Tel: (909) 861-7575 Fax: (909) 396-8706

Division of Standards and Labeling Regulations  
Office of Nutritional Products, Labeling and Dietary Supplement  
Center for Food Safety and Applied Nutrition  
FDA  
5100 Paint Branch Rd.  
College Park, MD 20740-3835



July 13, 2003

**RE: 75 DAYS PRE-MARKET NOTIFICATION LETTER FOR STATEMENT ON  
DIETARY SUPPLEMENT - Eighteen Buddha Ta Da Wan**

To whom it may concern,

As the consultant for Sumay Inc., I am sending you our application for 75 days pre-market notification for "Eighteen Buddha Ta Da Wan" (a dietary supplement product) per Section 413 (a)(2) of the Federal Food, Drug, Cosmetic Act.

I am attaching the literature to show the safety for human consumption for the new dietary supplement ingredients in "Eighteen Buddha Ta Da Wan (The website and printed information on the referenced information are stapled together). However, I also included literature on most of the other ingredients used in the product. We feel we have done our best to assure you the food safety of "Eighteen Buddha Ta Da Wan" for the intended use. About the Structure / functional claim, Please advise a best option for us.

Please inform me if there is/are any other requirements or amendments needed for the application.

Best Regards,

A handwritten signature in cursive script, appearing to read "David Hsu".

David Hsu,  
President

**Sumay Inc.**  
**1108 W. Valley Blvd., #4160**  
**Alhambra, CA 91803**  
**Tel: (626) 826-7989 Fax: (626) 280-3637**

Division of Standards and Labeling Regulations  
Office of Nutritional Products, Labeling and Dietary Supplement  
Center for Food Safety and Applied Nutrition  
FDA  
5100 Paint Branch Rd.  
College Park, MD 20740-3835

July 12, 2003

**RE: 75 DAYS PRE-MARKET NOTIFICATION LETTER FOR  
STATEMENT ON DIETARY SUPPLEMENT**

Dear FDA officers:

Per Code of Federal Regulation, Volume 21, part 101.93 (Section 413 (a)(2) of the Federal Food, Drug, Cosmetic Act), we are enclosing all the required documents for the filing of the pre-market notification on our new upcoming herbal product – “Eighteen Buddha Ta Da Wan”.

**1. Statement of Purpose**

This is a letter to provide notification of a statement of nutritional support, including the ingredient statement, supplement fact, new dietary supplement ingredient usage and safety data, the text for Structure / Function statement, finished product formulas, and clinical trial report.

**Company Information**

Sumay Inc.  
1108 W. Valley Blvd., #4160, Alhambra, CA 91803  
Tel: (626) 826-7989 Fax: (626) 280-3637

**New Century Company  
3392 Falcon Ridge Rd.  
Diamond Bar, CA 91765  
Tel: (909) 861-7575, Fax: (909) 396-8706**

Division of Standards and Labeling Regulations  
Office of Nutritional Products, Labeling and Dietary Supplement  
FDA  
5100 Paint Branch Parkway  
College Park, MD 20740-3835

Dear Vicki,

July 21, 2003

Per our telephone discussion today, I am faxing you two amended pages on our recent submission of pre-market notification on the dietary supplement product – "Eighteen Buddha Ta Wan" for Sumay Inc.

Please inform me for any questions. Thanks!

Sincerely

  
David Hsu

## Page 2

**2. Co-Packing Manufacturer for "Eighteen Buddha Ta Da Wan" :**

Cheong Chun Tong Factory  
Flat / Rm C 7/F  
Sunview Industry Building  
3 On Yip Street  
Chai Wan, Hong Kong

**3. FDA Consultant information:**

David Hsu  
3392 Falcon Ridge Rd.  
Diamond Bar, CA 91765  
Tel: (909) 861-7575, Fax: (909) 396-8706

**4. Product Identification:**

The trade name of the product Eighteen Buddha Ta Da Wan

The common and usual name for the product:

Muscle pain relieving pill

The label will read like this:

**5. Active ingredient:** Black Current powder, Blackberry powder, and Oil of sweet Birch powder.

**6. Supplement Facts:**

Serving size : 1 caplet per day  
Amount per serving: 2.0 g  
Serving per container: to be determined.  
Maximum dosage: 2 caplet per day.  
Duration of product use: 1 year.

**8. Active Ingredient Formula :**

	<u>Amt per serving</u>	<u>% Daily value</u>
Black Current powder	0.12 g	*
Blackberry powder	0.08 g	*
Oil of Sweet Birch powder	0.005 g	*

\* not established.

**9. The Text for Structure / Function statement:**

This formula helps your muscle health.

This statement has not been evaluated by FDA, this product is not intended to diagnose, treat, cure, and prevent any disease.

**10. New Dietary Supplement Ingredients in "Eighteen Buddha Ta Da Wan":**

---

<b>Common Name</b>	<b>Latin Binominal name</b>
Black current powder	Ribes nigrum
Blackberry powder	Cimicifuga racemosa
Oil of Sweet Birch	Betula alba L.

---



**2. Co-Packing Manufacturer for "Eighteen Buddha Ta Da Wan" :**

Cheong Chun Tong Factory  
Flat / Rm C 7/F  
Sunview Industry Building  
3 On Yip Street  
Chai Wan, Hong Kong

**3. FDA Consultant information:**

David Hsu  
3392 Falcon Ridge Rd.  
Diamond Bar, CA 91765  
Tel: (909) 861-7575, Fax: (909) 396-8706

**4. Product Identification:**

The trade name of the product Eighteen Buddha Ta Da Wan

The common and usual name for the product:

Muscle pain relieving pill

The label will read like this:

**5. Active ingredient:** Black Current powder, Blackberry powder, Tumeric root-tuber powder, and Oil of sweet Birch powder.

**6. Supplement Facts:**

Serving size: 1 capsule per day  
Amount per serving: 2.0 g  
Serving per container: to be determined.

*ALL  
Fax*

**8. Active Ingredient Formula :**

	<u>Amt per serving</u>	<u>% Daily value</u>
Black Current powder	0.12 g	*
Blackberry powder	0.08 g	*
Tumeric Root-Tuber powder	0.05 g	*
Oil of Sweet Birch powder	0.005 g	*

\* not established.

**9. The Text for Structure / Function statement:**

Option (1) This formula helps you to remove muscle pain.

Option (2) This formula maintains and enhances your muscle health.

Option (3) This formula helps your muscle health.

(please indicate which one is acceptable by FDA)

**10. New Dietary Supplement Ingredients in "Eighteen Buddha Ta Da Wan":**

<b>Common Name</b>	<b>Latin Binominal name</b>
Black current powder	Ribes nigrum
Blackberry powder	Cimicifuga racemosa
Tumeric Root-Tuber	Radix Curcumae
Oil of Swwt Birch	Betula alba L.

*DR. GAT*

All sourced from China

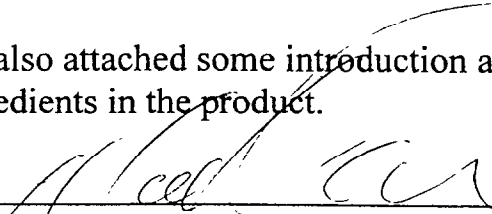
10. **Percentage of main active ingredient in the finished product – 79.365%**

11. **Each caplet weight: 1.0 g.**

We appoint Mr. David Hsu as our FDA regulation representative in U. S., for any future correspondence, please contact him, his address and contact no. are:

New Century Company  
3392 Falcon Ridge Rd.  
Diamond Bar, CA 91765  
Tel: (909) 861-7575

We also attached some introduction and clinical test literature on the active ingredients in the product.

  
\_\_\_\_\_  
Manuel Chau, General Manager  
Sumay Inc.